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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,154

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Iztok Klobcar

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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

08/19/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efspatents@sbiplaw.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/599,154	KLOBCAR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	GIGI HUANG	1612	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/4/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

**Request for Continued Examination**

***Status of Application***

1. The response filed June 3, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:
  - a. Claims 13-14 have been amended.
2. Claims 1-17 are pending in the case.
3. Claims 13-17 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.

***Information Disclosure Statement***

6. The information disclosure statement filed September 4, 2008 has been included with new annotations wherein the abstracts of certain EP documents have been considered as they have been included in the translation. It is noted that EP 1338951 has been corrected. The remaining EP documents cited by Applicant as being related to U.S. documents do not address which documents they are related to for consideration. Initial attempts to find patent families were unsuccessful as the EP site is currently unavailable. Clarification as to which U.S. references are related to the EP documents to be considered is requested.

***Priority***

7. Claims 13-15 are supported to receive priority to the DE 1020040198454 filed March 29, 2004. Claims 16-17 which is direct to the drug combination is supported only in DE 1020040595216 filed December 9, 2004 and given priority to December 9, 2004.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for free base of indapamide, does not reasonably provide enablement for hydrates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

Pursuant to *In re Wands*, 8 USPQ2d 1400, factors such as:

*(1) The nature of the invention and (2) the breadth of the claims:*

The claim is drawn to indapamide or a hydrate thereof. The specification, while enabling for the free base, it does not reasonably provide enablement for all its possible hydrates.

*(3) The state of the prior art and (4) the predictability or unpredictability of the art:*

Vippagunta et al. (Advanced Drug Delivery Reviews 48 (2001) 3-26) teaches that predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Certain molecular shapes and features favor the formulation of crystals without solvent. No computer programs are currently available for predicting the crystal structures of hydrates and solvates and generalizations cannot be made for a series of related compounds. [Page 18, 3.4]

Thereby resulting in high unpredictability in the art.

*(5) The relative skill of those in the art:*

The degree of skill in the art is high.

*(6) direction or guidance:*

None is seen in the specification. Not all solvents can form solvates with all compounds; there is no process present in the specification producing a final product that is a solvate;

*(7) presence or absence of working examples:*

There is no example of a hydrate in the present case which does not allow one to ascertain the entirety of the claimed genus, the scope, nor how to make the genus claimed;

*(8) quantity of experimentation needed:*

Considering the state of the art as discussed by the references above, particularly with regards to the teaching of Vippagunta et al. and the high

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unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to make the invention commensurate in the scope of the claims.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 14, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. It is unclear and does not allow one of skill in the art to ascertain the metes and bounds of the invention. For purposes of prosecution, only the ratio of 0.1-0.9 is examined.

12. Claim 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite that the components have "low moisture content" or are substantially anhydrous". This is unclear and confusing as there is no description or definition as to what degree of moisture would constitute a low moisture content for the components of the composition other than for the microcrystalline cellulose which is already indicated by the claims to be 0.3 to 5.0%, but there is nothing in the disclosure as to the metes and bounds for the remaining components of the composition. This is also the case with the term "substantially

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anhydrous” as there is no description or definition as to what level constitutes “substantially anhydrous” for the components of the composition. This is further confusing as the dependent claims 16 and 17 recite hydrates of indapamide which contain water and conflict with the terms. It does not allow one of skill in the art to ascertain the metes and bounds of the invention. For purposes of prosecution, any amount of hydration or moisture applies.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 13-14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guez et al. (WO 99/25374) in view of Eyjolfsson (WO 03/059388).

It is noted that Guez et al (U.S. Pat. 6653336) will be used as the translation for Guez et al. (WO 99/25374) and all references will be to the U.S. Pat.

Guez et al. teaches the combination of an angiotensin-converting enzyme inhibitor (ACE or CEI) and a diuretic in a pharmaceutical composition. Guez teaches the benefits of the combination and the preferred CEI particularly is perindopril and its salts. The preferred diuretic is indapamide and hydrochlorothiazide and their salts, more particularly indapamide. Examples teach the combination of perindopril and indapamide in pharmaceutical compositions with excipients including microcrystalline cellulose. Guez teaches the inclusion of excipients, binders, diluents, stabilizing agents, and other

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desirable components (Abstract, Col. 2 line 55-62, Col. 3 line 11-Col. 4 line 50). It is known in the art that microcrystalline cellulose is a moisture control agent and the commercially available products (such as Avicel®PH-101) generally have moisture contents of less than 5% (see Signet sheets). Guez also teaches several composition forms including instantaneous and delayed release. It is noted that the limitation of the DKP content at 3 week storage at 50°C in a closed container as written, would be intrinsic to a composition with perindopril, at least one of microcrystalline cellulose and anhydrous lactose, at least one inorganic carbonate, and optionally other components. As a result when the composition limitations are met, the properties would intrinsically be met.

Guez et al. does not expressly teach the use of a carbonate, or a molar ratio of 1 to 0.1-0.9 for perindopril to inorganic carbonate. Guez does teach the inclusion of excipients such as stabilizing agents in the formulation.

Eyjolfsson teaches the inclusion of components including of carbonates, particularly alkali or alkaline-earth metal carbonates produce useful and stable ACE inhibitor formulations. The ACE inhibitors taught include perindopril and the combination of diuretics. Eyjolfsson teaches a preferred embodiment of the amount of carbonate to at least the equivalent of the active. However, the general teaching of Eyjolfsson is to the inclusion of carbonates for the production of stable ACE inhibitor formulations and claims a composition with an ACE inhibitor including perindopril, at 0.5-50wt.%, and the alkali or alkaline earth metal carbonate at 5-90% encompassing ratios in the preferred embodiment such as 1:1 and ratios beyond the preferred embodiment, such as 1:0.5



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and 1:0.9 (see document, specifically Abstract, Page 2 line 5-16, page 3 line 24-25, Page 4 line 10-15, Claims 1-2, 4, 11).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include carbonates and optimize the molar ratio to the ACE inhibitor, as suggested by Eyjolfsson, and produce the instant invention.

It would have been obvious to incorporate components such as the carbonates of Eyjolfsson for ACE inhibitors like perindopril, as Eyjolfsson teaches the inclusion of carbonates improves the stabilization of ACE inhibitor and Guez teaches the inclusion of components for increased stabilization of a formulation. It would have been obvious to one of skill in the art to optimize the amount carbonate as the general teaching encompasses ratios below 1:1 as presented in the claims and the specification to affect the amount of stabilization for a pharmaceutical formulation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation as the adjustment of particular conventional working conditions, such as determining a suitable effective dosage in combination with other component ranges, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan to yield the desired properties in the composition.

One of ordinary skill in the art would have been motivated to do this because combining components that would provide a more stable composition and yield an increasingly effective and desirable product with better shelf life is desirable.

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15. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guez et al. (WO 99/25374) in view of Eyjolfsson (WO 03/059388) as applied to claim 13 and 14 above, in view of [www.signetchem.com](http://www.signetchem.com), and further in view of Cooper et al. (U.S. Pat. Publication 2003/0137067).

The teachings of Guez et al. in view of Eyjolfsson are addressed above.

Guez et al. in view of Eyjolfsson do not expressly teach the use of microcrystalline cellulose with a moisture content of 0.3-1.5% by weight. Guez does teach the inclusion of microcrystalline cellulose and the diuretic indapamide. Guez also teaches several composition forms including instantaneous and delayed release.

[www.signetchem.com](http://www.signetchem.com) teaches that a number of commercial microcrystalline celluloses with different properties, size, and forms were readily available for purchase and use in 2002 for one of skill in the art at the time of the invention to produce the product properties desired.

Cooper et al. teaches the use of nanoparticles of active agents with various particle sizes of other actives to obtain immediate-release and controlled-release forms. The actives include cardiovascular agents, cardiac inotropic agent, diuretic, and antihypertensive agents (Paragraph 35-37, 64-67, 94-102).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize any commercially available microcrystalline celluloses (e.g. Avicel®PH-112) and to modify the particle size of the drugs, in the

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composition taught by Guez, as suggested by [www.signetchem.com](http://www.signetchem.com) and Cooper, and produce the instant invention.

It would have been obvious at the time of the invention to purchase any appropriate microcrystalline cellulose such as Avicel®PH-112 to use and to modify the composition taught by Guez in view of Eyjolfsson as needed to arrive at a final product with the desired properties. It would have also been obvious to modify the teachings presented by Guez including particle size, to create products with any number of specialized forms and applications (e.g. immediate release, delayed release, etc.) depending on the drug release profile and form desired which is well within the skill of one in the art.

One of ordinary skill in the art would have been motivated to do this because it is more cost effective to purchase a commercial product than to produce the microcrystalline cellulose yourself, and the commercial product is desirable as it had consistent properties and uniformity in the mixture. One would have been motivated to modify the components (microcrystalline cellulose, particle size, etc.) to provide a number of materials that would be uniquely suited for the product use desired such as immediate release or controlled release compositions which are modifiable based on the components and/or particle size to yield the desired drug release profile.

16. Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (U.S. Pat. Publication 2005/0142196).

Patel et al. teaches a stable pharmaceutical composition comprising an ACE inhibitor, an alkali or alkaline earth metal carbonate, and microcrystalline cellulose. The

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ACE inhibitors taught for the composition and claimed include perindopril in the range of about 1 to about 80wt%, the carbonate is in the range of about 1 to 70wt.% with magnesium carbonate exemplified, and the microcrystalline cellulose is known in the art as a moisture control agent where the commercially available products (such as Avicel®PH-101) generally have moisture contents of less than 5% (see previous Signet and Avicel® sheets).

Patel teaches that the compositions can be prepared with conventional processing techniques such as dry granulation and wet granulation. Patel teaches that the composition may be in several forms including capsule, caplet, powder, disc, or tablets. Patel provides examples with quinapril, magnesium carbonate, and microcrystalline cellulose (Abstract, paragraph 1-5, 11-15, 23-44, 52-63, claims). It is noted that the limitation of the DKP content at 3 week storage at 50°C in a closed container as written, would be intrinsic to a composition with perindopril, at least one of microcrystalline cellulose and anhydrous lactose, at least one inorganic carbonate, and optionally other components. As a result when the composition limitations are met, the properties would intrinsically be met.

Patel does not expressly teach an example with perindopril or teach the use of a carbonate at a molar ratio of 1 to 0.1-0.9 for perindopril to inorganic carbonate. Patel does teach the composition to be for certain ACE inhibitors including perindopril, claims as such, and exemplifies with quinapril.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to exemplify the perindopril with the formulation taught by

Patel and optimize the molar ratio to the ACE inhibitor within the ranges taught by Patel, and produce the instant invention.

It would have been obvious at the time of the invention to exemplify the composition with all the taught and claimed ACE inhibitors of Patel as Patel teaches the formulations to be stable which is desirable as the use of ACE inhibitors for hypertension is well known (addressed by Patel paragraph 13). It would also be obvious to one of skill in the art to optimize the amount carbonate and the ACE inhibitor within the ranges taught by Patel to attain the desired amount of stabilization. As the general teaching and claims of Patel encompasses ratios below 1:1, when the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation as the adjustment of particular conventional working condition, such as determining a suitable effective component range, it is deemed merely a matter of routine optimization which is well within the purview of the skilled artisan to yield the desired properties in the composition.

One of ordinary skill in the art would have been motivated to do this because adjusting components to provide a more stable composition and yield an increasingly effective and desirable product with better shelf life is desirable.

17. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (U.S. Pat. Publication 2005/0142196) as applied to claim 13-14 above, in view of [www.signetchem.com](http://www.signetchem.com).

The teachings of Patel et al. are addressed above.

Patel et al. do not expressly teach the use of microcrystalline cellulose with a moisture content of 0.3-1.5% by weight. Patel does teach the inclusion of microcrystalline cellulose (paragraph 34 and examples) and the objective to improve the stability of the composition in the presence of moisture (paragraph 4).

[www.signetchem.com](http://www.signetchem.com) teaches that a number of commercial microcrystalline celluloses with different properties, size, and forms were readily available for purchase and use in 2002 for one of skill in the art at the time of the invention to produce the product properties desired.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize any commercially available microcrystalline celluloses (e.g. Avicel®PH-112) as suggested by [www.signetchem.com](http://www.signetchem.com), particularly one with as little moisture as desired in the composition as addressed by Patel, and produce the instant invention.

It would have been obvious at the time of the invention to purchase any appropriate microcrystalline cellulose such as Avicel®PH-112 to use and to modify the composition taught by Patel as needed to arrive at a final product with improved stability of the composition in the presence of moisture.

One of ordinary skill in the art would have been motivated to do this because it is more cost effective to purchase a commercial product than to produce the microcrystalline cellulose yourself, and the commercial product is desirable as it had consistent properties and uniformity in the mixture. One would have been motivated to

modify the components (e.g. type of microcrystalline cellulose) to improve the stability of the composition in the presence of moisture as addressed by Patel, with a number of materials that would be uniquely suited for the product use desired such as less moisture in the product.

18. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (U.S. Pat. Publication 2005/0142196) in view of [www.signetchem.com](http://www.signetchem.com), as applied to claim 15 above, in view of Guez et al. (WO 99/25374).

The teachings of Patel in view of [www.signetchem.com](http://www.signetchem.com) are addressed above.

Patel in view of [www.signetchem.com](http://www.signetchem.com) does not expressly teach the incorporation of indapamide.

Guez teaches the benefits of combining CEI with diuretics. The preferred CEI is perindopril and the more particularly preferred diuretic is indapamide. Examples teach the combination of perindopril and indapamide in pharmaceutical compositions with excipients including microcrystalline cellulose (Abstract, Col. 2 line 55-62, Col. 3 line 11-38, Example 1-2). Guez also teaches the drug combination can be in several composition forms including instantaneous and delayed release.

It is obvious to combine the perindopril with the indapamide which is taught by Guez to be useful not only for the hypertensive disorder but for the microcirculatory issues related to the condition by combining the two drugs.

One of ordinary skill in the art would have been motivated to do this because it is desirable to have and produce a composition comprising many components which have an improved and desirable effect for the disease and its related conditions.

19. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (U.S. Pat. Publication 2005/0142196) in view of [www.signetchem.com](http://www.signetchem.com) in view of Guez et al. (WO 99/25374), as applied to claim 15 above, further in view of Cooper et al. (U.S. Pat. Publication 2003/0137067).

The teachings of Patel in view of [www.signetchem.com](http://www.signetchem.com) in view of Guez et al. (WO 99/25374) are addressed above.

Patel in view of [www.signetchem.com](http://www.signetchem.com) in view of Guez does not expressly teach the particle size of indapamide.

Patel in view of [www.signetchem.com](http://www.signetchem.com) in view of Guez does teach the composition of perindopril with carbonate, microcrystalline cellulose with a moisture content of 0.3-1.5% by weight, and the benefit of the inclusion of diuretic indapamide, and that the combination can be in several composition forms including instantaneous and delayed release that would be encompassed in composition forms of Patel. Patel also teaches that components of the composition may be in preferred particle sizes such as hydroxypropyl cellulose which are preferred at an average particle size of 40 or 50 microns (paragraph 23-31).

Cooper et al. teaches the use of nanoparticles of active agents with various particle sizes of other actives to obtain immediate-release and controlled-release forms. The actives include cardiovascular agents, cardiac ionotropic agent, diuretic, and antihypertensive agents (Paragraph 35-37, 64-67, 94-102).



It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the particle size of the drugs depending on the release profile desired, as suggested by Cooper, and produce the instant invention.

It would have been obvious at the time of the invention to modify the particle size of the components, as suggested by Cooper to create products with any number of specialized forms and applications (e.g. immediate release, delayed release, etc.) depending on the drug release profile and form desired which is well within the skill of one in the art; as Patel already teaches having micronizing components of the composition such as the HPC wherein the preferred particle size is 40 or 50 microns (LH-21 and LH-11) and several composition forms.

One of ordinary skill in the art would have been motivated to do this because it is desirable to modify the components (e.g. HPC, drugs, particle size, etc.) to provide a number of materials that would be uniquely suited for the product use desired such as immediate release or controlled release compositions which are modifiable based on the components and/or particle size to yield the desired drug release profile.

### ***Response to Arguments***

20. Claim 13-14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guez et al. (WO 99/25374) in view of Eyjolfsson (WO 03/059388).

Applicant's arguments filed 6/3/2009 have been fully considered but they are not persuasive. Applicant asserts that the references do not recite the limitation of the DKP content at 3 week storage at 50°C in a closed container. As addressed above, the DKP as written would be intrinsic to a composition with perindopril, at least one of

microcrystalline cellulose and anhydrous lactose, at least one inorganic carbonate, and optionally other components. As a result when the composition limitations are met, the properties would intrinsically be met. It is noted that the claims should be commensurate in scope with any comparative presented. The arguments in regards to Eyjolfsson are not persuasive as the arguments are to an example in Eyjolfsson which is to different temperature and humidity conditions as well as to a related but different inhibitor and not commensurate in scope with the claims. Applicant's argument with regards to teaching away citing a negative proviso in Eyjolfsson for not containing a substantial amount of a saccharide is not persuasive as there is still the presence of saccharides taught in the art and is not commensurate in scope with the claims.

Accordingly, the rejection of claims is maintained.

21. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guez et al. (WO 99/25374) in view of Eyjolfsson (WO 03/059388) as applied to claim 13 and 14 above, in view of [www.signetchem.com](http://www.signetchem.com), and further in view of Cooper et al. (U.S. Pat. Publication 2003/0137067).

Applicant's arguments filed 6/3/2009 have been fully considered but they are not persuasive. Applicant's arguments are directed to the limitation of the DKP content at 3 week storage at 50°C in a closed container. As addressed above, the DKP as written would be intrinsic to a composition with perindopril, at least one of microcrystalline cellulose and anhydrous lactose, at least one inorganic carbonate, and optionally other components. As a result when the composition limitations are met, the properties would intrinsically be met.

Accordingly, the rejection is maintained.

***Conclusion***

22. Claims 13-17 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH  
/Zohreh A Fay/

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Primary Examiner, Art Unit 1612